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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/356,112 12/15/94 WEGMAN E WEG2

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WITZ, J EXAMINER

ART UNIT PAPER NUMBER

1808

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DATE MAILED: 10/02/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

10/02/95

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), no days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☒ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-15 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-15 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

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Part III DETAILED ACTION

Specification

1. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure and an adequate written description of the invention.

Applicants disclose and claim a method of reducing the amount of adipose tissue in an individual at selected locations by means of the injection of collagenase and a second proteinase. Applicants disclose this method as an alternative to liposuction. Applicants' showing is drawn to the injection of the claimed proteinase(s) into fat pads of rats followed by autopsy and visual inspection and weight of the fat pads after up to 14 days. However, Applicants' showing is insufficient to enable the claimed invention for the reasons set forth below.

With the procedure of liposuction, adipose tissue, comprised of adipocytes containing fat globules, is physically removed from the body, thereby reducing the absolute amount of fat present in

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the body at selected sites compared to those sites prior to the treatment. With the procedure of the claimed invention, while the connective tissue, i.e. the adipocytes, are broken apart from each other and broken open, the fat is still present in the body and the body must deal with it in some manner. Applicants make a statement at page 6 of the specification that "residue from adipose tissue in the treated location is at least partly metabolized." Applicants have in no way shown this to be true in a degree significant for the intent of the claimed invention. Unless the basal metabolism of the patient changes significantly, the fat present in the body will be maintained at its present level and will be deposited in adipocytes, either remaining at the site or at other sites, until metabolized. Applicants themselves indicate that rats treated as claimed for 14 days gained weight. See page 25, line 17 of the specification. Further, Applicants have failed to make any correlation between digestion of fat pads in rats and cosmetic benefit as this is the intended result of the claimed invention. Applicants' results are limited to observation of the rats for 14 days or less after treatment and while digestion of the tissue (not the fat) is noted and in fact, expected, it remains unclear and unpredictable that such treatment will result in any cosmetic benefit for the reasons discussed above. Finally, the disclosure of Guidicelli et al. indicates that a rat model appears to be unable to predict

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efficacy in humans as it is clear from the reference that rat adipocytes react in a metabolically different manner from human adipocytes particularly when treated with collagenase and trypsin.

Therefore, the showing of record is insufficient to enable the claimed invention as it would require the practitioner to engage in an undue amount of experimentation to practice the claimed invention and the practitioner would still not have a reasonable expectation of success.

Claim Rejections - 35 USC § 112

2. Claims 1-5 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102

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of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

4. Claims 1-15 are rejected under 35 U.S.C. § 103 as being unpatentable over Lee et al. combined with Guidicelli et al.

The claims are drawn to the reduction of adipose tissue at selected sites in the body comprising the introduction of collagenase and another proteinase into said tissue.

The reference teaches that collagenase plus chymopapain for the digestion of connective tissue. Adipose tissue is particularly disclosed as being effectively digested so as to obtain endothelial cells present therein. Guidicelli et al. discloses that it is conventional to use collagenase and trypsin for the purpose of digesting and isolating adipocytes.

It is noted that the Lee et al. reference discloses the effects of the claimed composition both in vitro and for in vivo application for the digestion of connective tissue wherever desired and as the claims call only for the reduction of adipose tissue, it would have been obvious and predictable to one of ordinary skill in the art to use conventional enzymes known to digest said tissue, regardless of its site the expected digestion, i.e. dissociating the cells of the tissue. Optimization of dose is well within the skill of the practitioner

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as the enzyme kinetics of collagenase and other enzymes based upon amount of substrate are well known.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073.

A handwritten signature in black ink, appearing to read 'Jean C. Witz', with a stylized, cursive script.

Jean C. Witz
Patent Examiner, Group 1800

September 27, 1995